St. Jude Medical Enrolls First Patient in ILUMIEN I Study to Develop Guidance for Stent Optimization

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Dec 18, 2012--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced the first patient enrollment in its ILUMIEN I clinical study. This observational study is designed to show the optimal way Optical Coherence Tomography (OCT), an intravascular imaging technology, combined with the St. Jude Medical PressureWire ™ Aeris, a wireless interventional tool that measures Fractional Flow Reserve (FFR), can guide stent implantation in patients with coronary artery disease. The study will observe and record how physicians treat patients while undergoing Percutaneous Coronary Intervention (PCI), and will also measure outcomes according to various procedural parameters. Commonly known as coronary angioplasty, PCI is a non-surgical procedure used to treat narrowed coronary arteries of the heart found in coronary artery disease. Gathering this information will assist in establishing guidance parameters for optimal stenting, which may result in improved clinical outcomes for patients undergoing PCI.

“Improving patients’ quality of life is our highest priority as physicians, and if we can successfully treat our patients while streamlining workflow, the benefit is even greater,” said Dr. David Holmes, ILUMIEN I Global Steering Committee Member and U.S. Coordinating Investigator from Mayo Clinic in Rochester, Minn. “The ILUMIEN I study is an important step towards guiding physician decisions during PCI, ultimately leading to better clinical outcomes.” OCT images allow physicians to visualize and measure important vessel characteristics for stent planning. Following stent placement, the high-resolution images offered by OCT show precisely how the stent is holding the artery open and whether it is positioned correctly against the artery wall, informing treatment and follow-up strategies. When combined with the PressureWire Aeris to measure FFR, the use of OCT potentially minimizes the need for urgent hospital visits, repeat revascularizations or other complications.

"OCT offers a remarkably clear image from inside the coronary vessel, which is something we haven't been able to see previously," said Prof. William Wijns, ILUMIEN I Global Steering Committee Member and International Coordinating Investigator from the Cardiovascular Center, Aalst, Belgium. "Using this technology, I can assess important vessel characteristics before placing the stent, confirm success after placing the stent, and identify potential problem areas to quickly understand how to best treat my patient." The ILUMIEN I prospective, observational study will enroll approximately 500 patients at 40 medical centers around the world. Patients will first undergo a catheterization procedure, which includes using the PressureWire Aeris to take FFR measurements and establish the severity of blood flow restriction to determine the level of treatment needed. In arteries where FFR has determined that treatment is needed, OCT images will then be collected to help inform stent selection and placement. Following stent placement, OCT images will

be collected again to help inform the physician regarding the need for additional intervention. Data will be collected before and after stenting, as well as throughout the twelve month follow-up period, to understand the impact of coronary lesion characteristics and stent deployment on patient outcomes. All collected data will be compiled and used in determining stent guidance parameters to achieve PCI optimization in both stable and unstable coronary disease patients.

“Our FAME family of trials have demonstrated the compelling value of FFR in the treatment of coronary artery disease, and we are now working with leaders in the field to develop further evidence of OCT use and how it can positively impact physician decision-making,” said Frank J. Callaghan, president of the Cardiovascular and Ablation Technology Division at St. Jude Medical. “We are confident that the ILUMIEN I study will result in establishing more efficient lab procedures for physicians and better treatment plans for patients.” Coronary artery disease is the most common type of heart disease and affects millions of people worldwide. It is caused by a narrowing or blocking of the arteries due to plaque build-up that restricts blood flow and reduces the amount of oxygen being delivered to the heart. In time, reduced blood flow may cause cardiac ischemia (coronary narrowing responsible for significantly obstructing the flow of blood to a patient’s heart muscle). A complete blockage can cause a myocardial infarction, also known as a heart attack.

The St. Jude Medical ILUMIEN™ PCI Optimization System is a more advanced option that can provide additional information and aid physicians in the treatment of coronary artery disease.

About the ILUMIEN System The ILUMIEN ™ PCI Optimization System features the St. Jude Medical PressureWire ™ Aeris, a wireless interventional tool that measures Fractional Flow Reserve (FFR) to evaluate the severity of blood flow blockages in the coronary arteries, and the St. Jude Medical Dragonfly™ Catheter, a first-to-market intravascular imaging catheter that allows physicians to visualize and measure important vessel characteristics otherwise not visible or difficult to assess with older intracoronary imaging technologies.

Combined, the two technologies enable the optimization of PCI procedures by assisting physicians in identifying culprit lesions responsible for ischemia. The technologies also provide physicians with precise measurements of lesion dimensions, as well as vessel size and structure.

About St. Jude Medical St. Jude Medical develops medical technology and services that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. The company is dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient. St. Jude Medical is headquartered in St. Paul, Minn. and has four major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. For more information, please visit sjm.com.

Forward-Looking Statements This news release contains forward-looking statements

within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. Such forward-looking statements include the expectations, plans and prospects for the Company, including potential clinical successes, anticipated regulatory approvals and future product launches, and projected revenues, margins, earnings and market shares. The statements made by the Company are based upon management's current expectations and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include market conditions and other factors beyond the Company's control and the risk factors and other cautionary statements described in the Company's filings with the SEC, including those described in the Risk Factors and Cautionary Statements sections of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and Quarterly Report on Form 10-Q for the fiscal quarter ended September 29, 2012. The Company does not intend to update these statements and undertakes no duty to any person to provide any such update under any circumstance.

CONTACT: St. Jude Medical, Inc.

J.C. Weigelt, 651-756-4347 Investor Relations jweigelt@sjm.com or Kristi Warner, 651-756-2085 Media Relations kwarner@sjm.com KEYWORD: UNITED STATES BELGIUM EUROPE NORTH AMERICA MINNESOTA INDUSTRY KEYWORD: SURGERY HEALTH BIOTECHNOLOGY CARDIOLOGY CLINICAL TRIALS MEDICAL DEVICES SOURCE: St. Jude Medical, Inc. Copyright Business Wire 2012 PUB: 12/18/2012 08:00 AM/DISC: 12/18/2012 08:00 AM
http://www.businesswire.com/news/home/20121218005067/

Source URL (retrieved on *09/23/2014 - 6:23pm*):
http://www.mdtmag.com/news/2012/12/st-jude-medical-enrolls-first-patient-ilumien-i-study-develop-guidance-stent-optimization?qt-most_popular=0&qt-video_of_the_day=0